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| 09/753,738      | 01/02/2001  | Geng Zhang           | 970663.CIP          | 3767             |

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[REDACTED] EXAMINER

SCHAETZLE, KENNEDY

[REDACTED] ART UNIT

PAPER NUMBER

3762

DATE MAILED: 08/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

NY

## Offic Action Summary

|                 |                   |                  |
|-----------------|-------------------|------------------|
| Application No. | 09/753,738        | Applicant(s)     |
| Examiner        | Kennedy Schaetzle | Art Unit<br>3762 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 02 May 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 43-64 is/are pending in the application.
- 4a) Of the above claim(s) 46-51 and 55 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 43-45,52-54 and 56-64 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)<br>6) <input type="checkbox"/> Other: _____ . |
|---|--|

**DETAILED ACTION**

***Election/Restrictions***

1. Newly submitted claims 46-51 and 55 are directed to an invention that is independent or distinct from the invention originally elected as set forth in the election of species requirement of paper no. 5.

Accordingly, claims 46-51 and 55 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Any submission of new claims by the applicants in future amendments must be accompanied by a statement indicating which of the newly submitted claims read on the elected invention. Simply stating that the independent claims are generic to all species will be considered an insufficient response.

***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 43-45, 52-54 and 56-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 17, 20, 21

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and 29-31 of U.S. Patent No. 6,169,921. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are merely broader than the patented claims. Once the applicant has received a patent for a species or a more specific embodiment, he is not entitled to a patent for the generic or broader invention (see *In re Goodman*, 11 F. 3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993)).

5. Claims 43-45, 52-54 and 56-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 16-19 and 26 of copending Application No. 09/206,329. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader versions of the claims in the copending application (note the citation above).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 43-45, 52-54 and 56-63 of this application conflict with claims 1, 8, 16-19 and 26 of Application No. 09/206,329. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

#### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 45, 52-54 and 56-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 45 is confusing in that it states that the system of claim 43 *further* comprises an atrial lead including at least one of an atrial tip electrode and an atrial ring electrode and a corresponding ventricular lead with ventricular electrodes. It is not clear if the recited tip and ring electrodes are electrodes in addition to those already recited in claim 43, or whether the applicant is simply further defining the existing electrodes of claim 43. The examiner will assume the later, but requests the applicant to refer back to the electrodes already recited in claim 43 (such as for example by using the definite article "the" or the word "said" to make it clear that one is referring back to an electrode that has already been set forth) when further defining them as atrial or ventricular ring or tip electrodes. A similar comment applies to claim 54.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 43-45, 52-54, 57-60, 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Silvian (Pat. No. 4,991,583).

Regarding claims 43 and 44, Silvian discloses a cardiac stimulation system including at least two electrodes selected from at least two groups of electrodes (see Fig. 3 and the use of atrial, ventricular and can electrodes), a stimulation system enclosed in a housing and electrically coupled to at least one atrial electrode and one ventricular electrode (again see Fig. 3 and the text abridging columns 10 and 11), a sensing circuit that senses an evoked response by the heart to the stimulus wherein the signal is sensed between at least two of the said electrodes (note for example the discussion of sensing between a ring electrode and a can electrode in col. 2, lines 28-36

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and col. 7, lines 1-34), and an afterpotential attenuation device for attenuating afterpotentials electrically coupled to the stimulation system (see the text abridging cols. 7 and 8).

11. Claims 43-45, 52-54 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Haefner et al. (Pat. No. 5,690,683).

Regarding claim 43, Haefner et al. disclose a cardiac stimulation system including at least two electrodes selected from at least two groups of electrodes including in the dual-chamber device of Haefner et al., atrial, ventricular and can electrodes. A stimulation system is coupled to at least one atrial and one ventricular electrode for providing electrical stimulus to at least one of an atrium or a ventricle of the heart (note pace pulse circuits 24 and 44 and their connection to electrode sets at terminals 22 and 42). An evoked response is sensed between at least two of said electrodes by a sensing circuit (note for example col. 5, line 35 – col. 6, line 57). An after potential attenuation means is clearly disclosed throughout the specification and explicitly mentioned for example in col. 8, lines 62-67.

Related comments apply to claim 44.

Regarding claims 45 and 52-54, note the discussion pertaining to the use of unipolar and bipolar electrode configurations in columns 5 and 6.

Concerning claim 64, Haefner et al. teach that one may utilize the same electrode or electrodes used in shocking and pacing for sensing as well (col. 10, lines 41-57). Haefner et al. also teach that an indifferent electrode may be substituted for a positive bipolar electrode, and that such an indifferent electrode may constitute a ring electrode (see col. 6, lines 34-57). Since by default if a remote indifferent bipolar ring electrode is replacing a positive bipolar ventricular or atrial electrode, the ring electrode must be in the opposite chamber since it is the only remaining ring electrode left that can be paired up with the negative bipolar electrode. One of the electrodes must therefore be a ventricular electrode and the other an atrial electrode.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haefner et al. (Pat. No. 5,690,683).

Concerning claim 56, Haefner et al. do not explicitly refer to the sensing of an evoked potential between an atrial ring electrode and a ventricular electrode. Haefner et al. teach that one may utilize the same electrode or electrodes used in shocking and pacing for sensing as well (col. 10, lines 41-57). Haefner et al. also teach that an indifferent electrode may be substituted for a positive bipolar electrode, and that such an indifferent electrode may constitute a ring electrode (see col. 6, lines 34-57). Since obviously if a positive bipolar ventricular or atrial electrode is being replaced by a remote indifferent bipolar ring electrode, the ring electrode must be in the opposite chamber since it is the only remaining ring electrode left that can be paired up with the negative bipolar electrode. Those of ordinary skill in the art would have therefore considered the use of an atrial ring electrode in combination with a ventricular electrode a matter of obvious design given the suggestion to pair an indifferent ring electrode with the negative bipolar electrode as opposed to the corresponding positive bipolar ring electrode. The decision to use an atrial ring electrode or a ventricular ring electrode as the indifferent electrode would have been dependent upon which chamber stimulation or sensing was desired in, and therefore entirely situation dependent.

14. Claims 43-45, 52-54 and 56-64 are rejected under 35 U.S.C. 103(a) as being obvious over Greeninger et al. (Pat. No. 5,324,310) in view of Zhu et al. (Pat. No. 5,843,136).

The applied Zhu et al. reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it

constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Greeninger et al. disclose the recited invention with the exception of the afterpotential attenuation means comprising first and second coupling capacitors of less than 5 microfarads and greater than 10 microfarads respectively. Greeninger et al. teach that an EGM signal sensed between atrial and ventricular ring electrodes is relatively unaffected by the afterpotentials that arise when the same lead is used for pacing and sensing. The term "relatively unaffected" infers that while afterpotentials may not affect the operation of the sensing amplifier to the same extent that would occur in the absence of ring-to-ring sensing, such potentials are still present and may thus affect device operation. Zhu et al. disclose an afterpotential attenuation system comprising the recited capacitor arrangement, and teach that this is a most effective way of reducing afterpotentials in devices such as disclosed by Greeninger et al.. Any artisan aggressively concerned with further reducing the possibility that afterpotentials may negatively affect device operation, would have seen the incorporation of an extra "layer" of defense such as disclosed by Zhu et al. to be a matter of obvious design with the number of layers limited only by the cost, complexity, and desired tolerances and acceptable afterpotential levels in the end product.

**Conclusion**

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

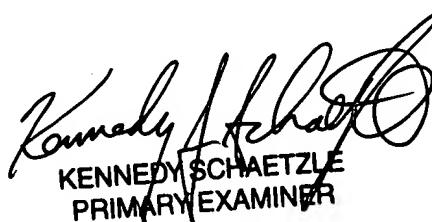
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is (703) 308-2211. The examiner can normally be reached on M-F from 9:30 - 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

KJS  
July 26, 2003

  
KENNEDY SCHAETZLE  
PRIMARY EXAMINER